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10/603,000

06/23/2003

David S. F. Young

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7590

04/25/2006

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EXAMINER

BLANCHARD, DAVID J

ART UNIT

PAPER NUMBER

1643

DATE MAILED: 04/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/603,000

Applicant(s)

YOUNG ET AL.

Examiner

David J. Blanchard

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9-14 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 15-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Group II, claims 9-14 in the reply filed on 13 February 2006 is acknowledged.

Applicants request for rejoinder of process claims 1-8 and 15-18 in accordance with *In re Ochiai*, *In re Brouwer* is acknowledged, however, in view that the elected product claims are not in condition for allowance for reasons set forth herein, the restriction requirement among Groups I-III is maintained. Applicant is reminded that in order to be eligible for rejoinder, a claim to a nonelected invention must depend from or otherwise require all the limitations of an allowable claim. A withdrawn claim that does not require all the limitations of an allowable claim will not be rejoined. See MPEP 821.04. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971) and MPEP § 804.01. An amendment presenting claims 1-8 and 15-18 that depend from or otherwise require all the limitations of an allowable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

2. Claims 1-8 and 15-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.
3. Claims 9-14 are under examination.

***Information Disclosure Statement***

4. The Information Disclosure Statement (IDS) filed June 29, 2005 has been fully considered and an initialed copy of the IDS is included with this Office Action.

***Specification***

5. The disclosure is objected to because of the following informalities:

a. The instant specification at pg. 8, line 4 refers to U.S. Patent 6,180,370 as disclosing the process used for the production of mouse monoclonal antibody H460-16-2, however, U.S. Patent 6,180,370 discloses the production of humanized antibodies. It is noted that pg. 6, line 15 and pg. 7, lines 6-8 of the instant specification state that the instant application uses the process disclosed in U.S. Patent 6,180,357 for isolating hybridoma cell lines. Clarification and/or correction are/is requested.

b. The top of Table 9 at pg. 38 of the specification is missing.

c. The specification is objected to for improper arrangement. As provided in 37 CFR 1.77(b), the specification of a utility application should include a Background of the Invention followed by a Brief Summary of the Invention followed by a Brief Description of the Drawings and a Detailed Description of the Invention. See MPEP 608.01(a). The instant specification does not contain a "Brief Summary of the Invention" and it appears applicant's "Summary of the Invention", beginning at pg. 6 is the Detailed Description of the Invention, including the disclosed examples. Thus, a "Brief Summary of the Invention" should be added at pg. 6, followed by the Brief Description of the Drawings, followed by a Detailed Description of the Invention. Applicant should delete the heading

"Detailed Description of the Invention" at pg. 16, line 3. Applicant's Brief Description of the Figures is noted on pages 16-18 of the specification.

Appropriate correction is required.

***Claim Rejections 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 9-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 9-13 are indefinite in the recitation "An isolated monoclonal antibody or antigen-binding fragments thereof encoded by the clone deposited with the ATCC as PTA-4621." in claim 9. The knowledge of those skilled in the art is such that a hybridoma or B cell-myeloma hybrid, secretes or produces mouse antibodies of a single idotype (see Campbell et al, Biology, 5<sup>th</sup> ed. pg. 856, 1999). The specification discloses that the clone deposited with the ATCC as PTA-4621 is hybridoma cell line H460-16-2 (see pg. 18). Thus, it is not clear what is contemplated by the phrase "encoded by the clone deposited with the ATCC as PTA-4621", since hybridomas secrete or produce monoclonal antibodies, but do not "encode" monoclonal antibodies (including humanized and chimeric monoclonal antibodies) and hybridomas do not secrete, produce or encode antigen-binding antibody fragments. While one skilled in the art could produce antigen-binding antibody fragments from the monoclonal antibody

produced by the hybridoma deposited under ATCC Accession No. PTA-4621, it is not clear what is contemplated by antigen-binding fragments that are “encoded by the clone deposited with the ATCC as PTA-4621”.

b. Claims 10-13 recite the limitation “The isolated antibody or antigen binding fragments of claim 9”. There is insufficient antecedent basis for this limitation in the claim. Claim 9 recites “An isolated monoclonal antibody and antigen binding fragments thereof” and it is unclear if dependent claims 10-13 are referring to the isolated monoclonal antibody produced by the hybridoma deposited under ATCC Accession No. PTA-4621 or some other antibody that is *encoded* by the clone deposited with the ATCC as PTA-4621 and what monoclonal antibodies and antigen-binding fragments are *encoded* by the clone deposited with the ATCC as PTA-4621?

### ***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 9-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant’s referral to the hybridoma deposit (PTA-4621) on page 18 of the specification that the hybridoma cell line H460-16-2 was deposited in accordance with the Budapest treaty with the ATCC on September 4, 2002, under Accession Number

Art Unit: 1643

PTA-4621 and that *all restrictions imposed on the availability to the public of the deposited materials will be irrevocably removed upon the granting of a patent*, is acknowledged, however, this is insufficient assurance that all of the conditions of 37 CFR 1.801-1.809 have been met in view of Applicant's earlier effective filing date, i.e., 10/8/1999. If a deposit is made after the effective filing date of the application for patent in the United States, as in the instant application, a verified statement is required from a person in a position to corroborate that the biological material described in the specification as filed is the same as that deposited in the depository, stating that the deposited material is identical to the biological material described in the specification and was in the applicant's possession at the time the application was filed. See MPEP 2406 and 37 CFR 1.804(b).

Applicant's attention is directed to In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

### ***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 9-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated monoclonal antibody (H460-16-2) produced by the hybridoma deposited under ATCC Accession No. PTA-4621 or an

Art Unit: 1643

antigen-binding fragment of said monoclonal antibody and chimeric, humanized and conjugated (i.e., cytotoxic moieties, enzymes, radionuclides, ect) forms of monoclonal antibody H460-16-2, does not reasonably provide enablement for an isolated monoclonal antibody or antigen-binding fragments thereof *encoded* by the clone deposited with the ATCC as Accession No. PTA-4621 and conjugates thereof or wherein the *encoded* antibody is a humanized or chimerized antibody. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 1 12, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). Wands states on page 1404,

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention is monoclonal antibody technology/hybridoma production, engineered monoclonal antibodies and cancer immunotherapy using cancer specific monoclonal and engineered antibodies, where the relative skill of those in the art is deemed to be high.

The claims are broadly drawn to an isolated monoclonal antibody or antigen-binding fragments thereof *encoded* by the clone deposited with the ATCC as Accession



No. PTA-4621 and conjugates thereof and wherein the isolated monoclonal antibody is a chimerized or humanized and antigen-binding fragments thereof. Thus, as broadly claimed, the claims encompass a genus of monoclonal antibodies and antigen-binding fragments thereof *encoded* by the clone deposited with the ATCC as Accession No. PTA-4621 including chimeric and humanized antibodies and antigen-binding fragments thereof *encoded* by the clone deposited with the ATCC as Accession No. PTA-4621.

The specification teaches that the hybridoma cell line H460-16-2 that produces the anti-cancer antibody deposited with the ATCC under Accession No. PTA-4621 (pg. 18) was produced utilizing the method disclosed in applicant's previous patent, U.S. Patent 6,180,357, wherein Balb/c mice were immunized with cells from a patient's lung tumor biopsy (see pp. 6 and 8 of the present specification), isolating the spleen and fusing the isolated spleen cells (i.e., B cells) with myeloma cells (NS-1) resulting in B cell-myeloma hybrids, or hybridomas, which are screened for the desired monoclonal antibody. The specification does not teach how to produce the clone/hybridoma deposited with the ATCC under Accession No. PTA-4621 wherein the clone *encodes* a monoclonal antibody or produces a monoclonal antibody that is not monoclonal antibody H460-16-2 (i.e., the monoclonal antibody produced by hybridoma H460-16-2), or wherein the clone *encodes* or produces antigen-binding antibody fragments, chimeric and humanized antibodies commensurate in scope with the claims. There are no working examples of the clone deposited with the ATCC under Accession No. PTA-4621 wherein the clone *encodes* a monoclonal antibody or produces a monoclonal

Art Unit: 1643

antibody other than monoclonal antibody H460-16-2, or *encodes* or produces antigen-binding antibody fragments, chimeric and humanized antibodies.

The state of the prior art is such that it is well established that the production of a monoclonal antibody requires immunizing a mouse with an antigen, once the immune response has developed, the mouse's spleen is removed, the spleen cells include many different antigen-reactive B cells as well as B cells specific for other antigens to which the mouse has recently been exposed. The spleen cells are then fused with myeloma cells, which are cancer cells that provide the resultant B cell-myeloma hybrid, or hybridoma, with the capacity to proliferate indefinitely. Thus, the B cells are "immortalized" and are an unlimited source of the antibody they secrete and the resultant hybridomas are tested and selected for the production of the desired monoclonal antibody (see Campbell et al, Biology, 5<sup>th</sup> ed. pg. 856, 1999). Co et al (Nature, 351(6):501-502, June 6, 1991) teach that a chimeric antibody combines the entire variable or binding domain of a mouse antibody with a human antibody constant, or Fc domain and a humanized antibody combines the CDRs from a rodent antibody (e.g., mouse antibody) into a human variable region framework and a human constant region (see Figure 1). One skilled in the art could not predictably produce any hybridoma or even the hybridoma deposited with the ATCC under Accession No. PTA-4621 that *encodes* a monoclonal antibody or antigen-binding fragments thereof or *encodes* or produces chimeric and humanized antibodies because the teachings and exemplification in the specification and the teachings in the prior art are such that a hybridoma is an immortalized antigen-specific mouse B cell (i.e., B cell-myeloma

Art Unit: 1643

hybrid), which secretes or produces mouse antibodies of a single idotype (i.e., the monoclonal antibodies produced from a given hybridoma are identical). While the art recognizes the ability to produce monoclonal antibodies or custom-made antibodies such as antigen-binding antibody fragments and chimeric and humanized antibodies (e.g., Co et al, supra) that are tailored *in vitro* through genetic engineering/recombinant DNA techniques, the art does not teach such antibody forms produced by a hybridoma indicating the high degree of unpredictability in the art as it pertains to the claimed invention. There is no guidance or direction provided by applicant to assist the skilled artisan in producing a hybridoma or the hybridoma deposited with the ATCC under Accession No. PTA-4621 that *encodes* a monoclonal antibody or that *encodes* or produces antigen-binding antibody fragments, chimeric and humanized antibodies, which comprise genetic elements of human antibodies that are not encoded in the genetic material of mouse B cells or the genetic material of myeloma cells used for producing a hybridoma. There is insufficient evidence or nexus for producing a hybridoma containing the human genetic elements of a chimeric and humanized antibody such that the hybridoma, or more particularly, the hybridoma deposited with the ATCC under Accession No. PTA-4621 *encodes* a monoclonal antibody that combines the entire variable or binding domain of a mouse antibody with a human antibody constant domain (i.e., chimeric antibody) or *encodes* an antibody that combines the CDRs from a mouse antibody and human framework and constant regions (i.e., humanized antibody). One of skill in the art could not extrapolate the teachings in the specification limited to a process for producing the H460-16-2

Art Unit: 1643

hybridoma (ATCC Accession No. PTA-4621) that produces mouse monoclonal antibody H460-16-2, wherein the spleen cells of Balb/c mice were fused with myeloma cells following immunization with cells from a patient's lung tumor biopsy to a process for producing the hybridoma deposited with the ATCC under Accession No. PTA-4621 that *encodes* a monoclonal antibody or that *encodes* or produces antigen-binding antibody fragments, chimeric and humanized antibodies with a reasonable expectation of success. The scope of the claims must bear a reasonable correlation with the scope of enablement. See In re Fisher, 166 USPQ 19 24 (CCPA 1970).

In view of the lack of the predictability of the art to which the invention pertains as evidenced by Campbell et al and Co et al, the lack of guidance and direction provided by applicant, and the absence of working examples, undue experimentation would be required to practice the claimed monoclonal, chimeric and humanized antibodies *encoded* by the clone deposited with the ATCC as Accession No. PTA-4621 with a reasonable expectation of success, absent a specific and detailed description in applicant's specification of how to effectively practice the claimed invention, and absent working examples providing evidence which is reasonably predictive of the claimed monoclonal antibodies *encoded* by the clone deposited with the ATCC as Accession No. PTA-4621, commensurate in scope with the claimed invention.

### ***Double Patenting***

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

Art Unit: 1643

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 9-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23-24 of copending Application No. 10/713,642 in view of Queen et al (U.S. Patent 5,530,101, issued 6/25/1996). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant claims are interpreted as being drawn to an isolated monoclonal antibody (H460-16-2) produced by the clone deposited with the ATCC as Accession No. PTA-4621 and antigen-binding fragments of said monoclonal antibody and conjugates thereof (i.e., cytotoxic moiety, enzyme, radionuclide, ect) and chimeric and humanized antibodies and antigen binding fragments thereof of said monoclonal antibody as well as the clone deposited under ATCC Accession No. PTA-4621.

Claims 23-24 of copending Application No. 10/713,642 are drawn to anti-cancer antibodies and fragments thereof produced by the various hybridomas including the

Art Unit: 1643

hybridoma designated as ATCC Accession No. PTA-4621 and anti-cancer antibodies and fragments thereof including monoclonal antibody H460-16-2. As evidenced by the instant specification hybridoma H460-16-2 produces monoclonal antibody H460-16-2 and is deposited under ATCC Accession No. PTA-4621 (see pg. 18). Claims 23-24 of copending Application No. 10/713,642 do not recite the hybridoma deposited under ATCC Accession No. PTA-4621 or chimeric, humanized and conjugated forms of monoclonal antibody H460-16-2 produced by the hybridoma deposited under ATCC Accession No. PTA-4621, wherein the conjugated forms are attached to a cytotoxic moiety, an enzyme, a radioactive compound or hematogenous cells. These deficiencies are made up for in the teachings of Queen et al.

Queen et al teach chimeric and humanized antibodies that are less immunogenic in human patients compared to mouse antibodies and hence, better suited for human therapy (see entire document, particularly columns 1-2, 11-16). Queen et al also teach monoclonal antibody conjugates comprising a cytotoxic moiety, enzyme or radionuclide for therapeutic benefit in human cancer patients (see columns 19-20).

Claims 9-14 in the instant application are obvious variants of claims 23-24 of copending Application No. 09/713,642 because it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to have obtained the hybridoma deposited under ATCC Accession No. PTA-4621 and produce chimeric, humanized and conjugated forms of monoclonal antibody H460-16-2 produced by the hybridoma deposited under ATCC Accession No. PTA-4621, for therapeutic benefit in human cancer patients.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success at the time the invention was made to have obtained the hybridoma deposited under ATCC Accession No. PTA-4621 and produce chimeric, humanized and conjugated forms of monoclonal antibody H460-16-2 produced by the hybridoma deposited under ATCC Accession No. PTA-4621, for therapeutic benefit in human cancer patients in view of Queen et al because Queen et al teach that chimeric and humanized antibodies are less immunogenic in human patients compared to mouse antibodies and hence, better suited for human therapy and Queen et al also teach monoclonal antibody conjugates comprising a cytotoxic moiety, enzyme or radionuclide for therapeutic benefit in human cancer patients. Therefore, one of ordinary skill in the art would have been motivated at the time the invention was made to have obtained the hybridoma deposited under ATCC Accession No. PTA-4621 and produced chimeric and humanized forms of monoclonal antibody H460-16-2 that are less immunogenic in human cancer patients. Further, one of ordinary skill in the art at the time the invention was made would have been motivated to conjugate monoclonal antibody H460-16-2 produced by hybridoma PTA-4621 to a cytotoxic moiety, an enzyme or a radionuclide for therapeutic benefit in cancer patients. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have obtained the hybridoma deposited under ATCC Accession No. PTA-4621 and produce chimeric, humanized and conjugated forms of monoclonal antibody H460-16-2 produced by the hybridoma deposited under ATCC Accession No. PTA-4621, for therapeutic benefit in

human cancer patients in view of claims 23-24 of copending Application No. 10/713,642 and Queen et al.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 9-14 are directed to an invention not patentably distinct from claims 23-24 of commonly assigned copending Application No. 10/713,642. Specifically, see above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned copending Application No. 10/713,642, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.



### Conclusion

15. No claim is allowed.
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,  
David J. Blanchard  
571-272-0827

